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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,081

12/21/2005

Martin Schlun

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EXAMINER

TANNER, JOCELYN C

ART UNIT

PAPER NUMBER

4133

NOTIFICATION DATE

DELIVERY MODE

05/30/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com

akron-docket@hotmail.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,081	<b>Applicant(s)</b> SCHLUN, MARTIN	
	<b>Examiner</b> JOCELIN C. TANNER	<b>Art Unit</b> 4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/13/2005</u> .                                               | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is in response to the application filed on December 21, 2005 in which claims 1-16 are presented for examination.

#### ***Status of Claims***

Claims 1-16 are pending, of which 1 is in independent form. Claims 1-6 and 8-16 are rejected under 35 U.S.C. 102(b) and claims 7 and 8 are rejected under 35 U.S.C. 103(a).

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 6/13/2005 was filed before the mailing date of the patent application on 12/21/2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the various axes, central axis, hinge axis and reference axis, as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Further, the drawings appear to be copies due to heavy shading making features of the Applicant's invention unclear. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are

required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "30" has been used to designate both hinge struts and spring struts in the specification, page 10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be

notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the recitation “a respective central axis of the hinge struts is simultaneously pivoted about a hinge axis extending transversely with respect to the bearing structure” in lines 13-15, renders the claim vague and indefinite since the claim does not define the reference points for the central axis, hinge axis and reference axis or how the central axis, hinge axis and reference axis are defined with respect to structure recited in the claim.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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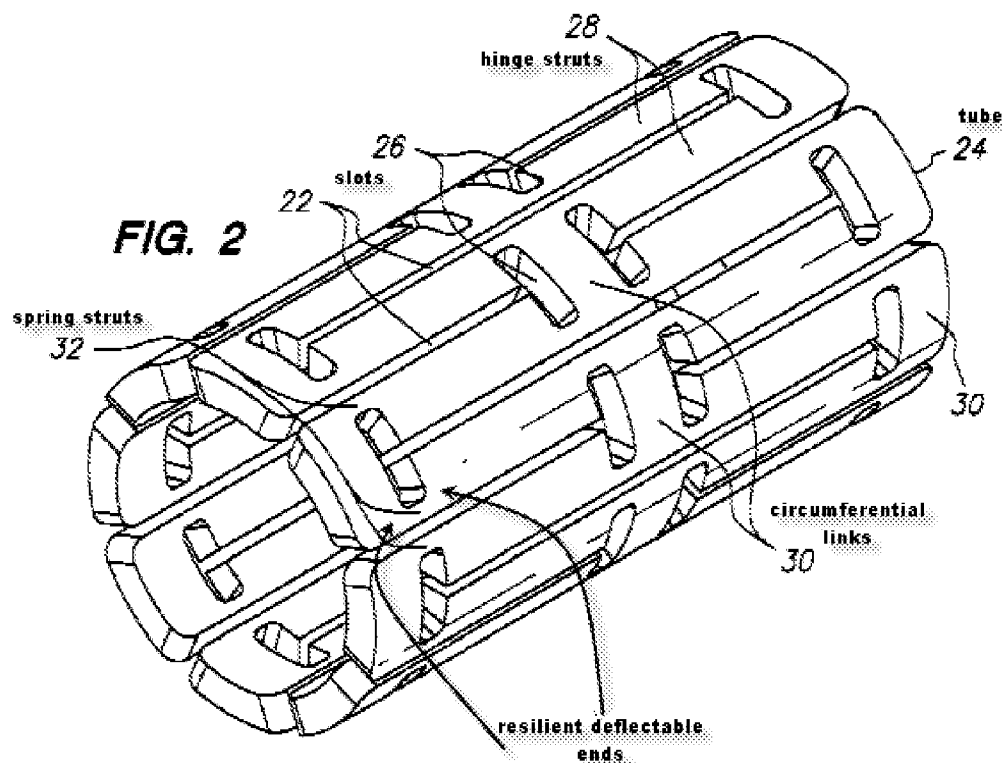
applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. As best understood in light of the rejection under 35 U.S.C. 112, second paragraph, claims 1-6 and 9-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Shanley (US Patent 6,562,065).

Regarding claim 1, Shanley discloses a one-piece expandable flat tissue supporting device or "bearing structure" (column 5, lines 47-48, FIG. 2, element #20) including at least partially elastically deformable struts (column 7, line 37) that change from elastic to largely plastic deformation which are separated from each other by slots or "openings" (FIG. 2, element #22 and #26) in the bearing structure, wherein the bearing structure can assume at least one compressed condition and at least one expanded condition (column 10, lines 48-52) and has at least one expansion direction, wherein:

the bearing structure has circumferential links or "anchor regions" (FIG. 2, element #30) extend to a resiliently deflectable end of the ductile hinges or "spring struts" (FIG. 2, element #32). Ductile hinges or "spring struts", which are elastically resilient with respect to the anchor regions (column 6, lines 52-53) wherein the insertion of ductile hinges increase the stiffness of the struts. A strut or "hinge strut" adjoining end, wherein the ductile hinges or "spring struts" and the struts or "hinge struts" (FIG. 2, element #28) are of such a configuration and arrangement that the ductile hinges or "spring struts" are initially resiliently deflected transversely to the expansion direction during the transition from the compressed condition to the expanded condition by the folding-over hinge

struts and finally spring back (column 6, lines 40-41) wherein the stent is crimped onto a catheter balloon and when expanded there is elastic springback while the struts are pivoted about the longitudinal axis (FIG. 9b) with respect to the bearing structure so that both the compressed condition of the bearing structure and also the expanded condition of the bearing structure is stabilized by a spring action emanating from the spring struts (column 6, lines 55-57).



6. Regarding claim 2, Shanley discloses a respective ductile hinge or “spring strut” (FIG. 2, element #32) adjoining both longitudinal ends of a respective strut or “hinge strut” (FIG. 2, element #28) and two spring struts are so arranged relative to each other

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that they exert a moment in the same direction on the strut or “hinge strut” about the hinge axis wherein the rotating motion of the hinge strut is produced as a result of the arrangement of the ductile hinges or “spring struts”.

7. Regarding claim 3, Shanley discloses two ductile hinges or “spring struts” respectively adjoining a strut or “hinge strut” are shaped and arranged in point-symmetrical relationship (FIG. 3a) with each other wherein each structural feature is symmetrical with respect to the longitudinal axis of the tissue supporting device.

8. Regarding claim 4, Shanley discloses a peripheral wall of a tube or “stent” (FIG. 2, element #24) in which the circumferential links are situated on the periphery of the tube.

9. Regarding claim 5, Shanley discloses an expansion direction extending in the peripheral direction of the stent and the reference axis extends parallel or at a shallow angle to the longitudinal direction of the stent while the hinge axis is oriented approximately radially with the struts or “hinge struts” opened vertically (FIG. 9b). The device expands vertically and horizontally without axial contraction unless the vertical expansion continues beyond a specified point.

10. Regarding claim 6, Shanley discloses a tissue supporting device or bearing structure made of plastic material (column 9, line 38).



11. Regarding claim 9, Shanley discloses slots or “openings” that are cut so that the struts are separated from each other by cuts (FIG. 2, elements #22, and #26) wherein the slots are formed through laser cutting (column 9, line 41).

12. Regarding claim 10, Shanley discloses cuts of such a configuration as to afford struts or “hinge struts” (FIG. 2, element #28) which are S-shaped or W-shaped in the compressed condition.

13. Regarding claims 11 and 16, Shanley discloses cuts having end regions which are of an expanded configuration (FIG. 2, element #26) to reduce the notch effect and have no point concentration of stresses and strains occur during expansion that would increase deformation.

14. Regarding claim 12, Shanley discloses ductile hinges or “spring struts” in the proximity of the circumferential links or “anchor regions”, are of a larger cross-sectional area than in the region of their resiliently deflectable ends (FIG. 3e) wherein the ductile hinge or “spring strut” is concave or convex and the thickness may vary as long as the width is constant along a portion of the ductile hinge since the tensile strain will be distributed along the surface during expansion (column 8, 35-37), thus allowing the deflectable ends to be of a smaller cross-sectional area.

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15. Regarding claim 13, Shanley discloses ductile hinges or “spring struts” that steadily taper from the circumferential links or “anchor regions” towards the resiliently deflectable ends (FIG. 2).

16. Regarding claim 14, Shanley discloses struts or “hinge struts” that are of a substantially uniform cross-section transversely with respect to their central axis (FIG. 2, element #28) wherein the struts have a constant cross section until the ends reach the circumferential slots (FIG. 2, element #26).

17. Regarding claim 15, Shanley discloses a transitional region of a cross-section which is reduced in relation to the strut or “hinge strut” and is provided between a respective resiliently deflectable end of a ductile hinge or “spring strut” and a strut or “hinge strut” adjoining the resiliently deflectable end.

### ***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley (US Patent No. 6,562,065) in view of Wu et al (US Patent No. 6,254,632).

Regarding claims 7 and 8, Shanley discloses all of the limitations previously

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discussed in claim 1 except for the tissue supporting device or "bearing structure" being formed of a magnesium alloy or a bioresorbable material (column 9, lines 35-38).

Wu et al teach an implantable medical device, i.e. a stent, that can be made of magnesium or combinations thereof or a bioabsorbable polymer (column 4, lines 47-48, and 54).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the Shanley device of a magnesium alloy or a bioabsorbable polymer, as taught by Wu, since it was well known in the art to have selected the material to construct a stent.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lee et al (US Patent No. 5,776,181), Ainsworth et al (US Patent No. 6,626,935), Frantzen (US Patent No. 6,042,606) and Hong et al (US Patent No. 6,805,705) are related to expandable stents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/  
Examiner, Art Unit 4133

5/22/2008

/Frantz Coby/  
Supervisory Patent Examiner  
Art Unit 4133